



Illustration by Shonagh Rae

“We Really Should Be Talking About an Ethics of Policymaking, Not Just the Bare-Knuckle Politics of Policymaking.”

R. Alta Charo gives a bioethicist’s perspective on vaccine mandates, the regulation of CRISPR gene-editing technology, and balancing society’s collective interests with personal liberties.

From stem cells and cloning, to CRISPR and chimeras, lawyer and bioethicist R. Alta Charo has been a key player in informing policymakers and the public on the implications of new technologies. She served on President Clinton's National Bioethics Advisory Commission and was an advisor at the Food and Drug Administration from 2009 to 2011. She is the Warren P. Knowles Professor Emerita of Law and Bioethics at the University of Wisconsin–Madison and the David A. Hamburg Distinguished Fellow at the Nuclear Threat Initiative. In a conversation that took place amidst new calls to investigate whether so-called gain-of-function research played a role in the beginning of the COVID-19 pandemic, *Issues in Science and Technology* editor William Kearney asked Charo about the ethics of such controversial research, the vaccine rollout, and how to balance society's collective interests with personal liberties.

You were a member of the National Academy of Medicine committee that advised officials last year on the equitable allocation of vaccines. Now that more than half the country is vaccinated, and with the benefit of hindsight, how would you think differently about allocation?

Charo: We spent a tremendous amount of time struggling with questions of equity, intention, and efficiency. We wanted to get the vaccine out as fast as possible, but often the people who are the most in need are the most difficult to reach. And which aspects of equity should we focus on? Should we favor those who have the most to lose in terms of years of life or those who are most likely to pass the virus along to somebody else if they don't get vaccinated? And so, we tried to balance individual and collective need in our report, in which we came up with fairly narrow, precise categories for phasing in the vaccine. That took a tremendous amount of time, and a lot of debate, and the recognition that this isn't perfect.

But then, when the vaccines actually got out into the world, we discovered that it doesn't make sense to leave a few vials unused and wasted at the end of the day, after you've finished with everybody in the first category—so you wind up immediately beginning to blur the boundaries between categories one and two. The next thing you realize is that sometimes, if you get to a vulnerable population, you really want to take advantage of being on-site. For example, when you go to vaccinate a senior who lives in a crowded housing situation, are you really not going to take advantage of

the fact that you could get the whole family vaccinated?

Then, because the public health system has been strained and underfunded for decades, you begin to see the distribution of vaccines under pressure. We do not have the kind of artificial intelligence or shipping and transportation capacities that would allow for an organized and rapid diffusion of vaccines to exactly where they need to go. All of these real-world phenomena began to get in the way of our pristine categories.

As I watched vaccines rolling out, I began to think that we should not have tried as hard as we did to have such precise phases of implementation. We might have said that we need to identify and prioritize those geographic areas that seem to be hot spots. I am looking forward to hearing from the people who were on the ground.

How does bioethics fit into the issue of vaccine hesitancy?

Charo: There is a very fundamental issue at the core of public health ethics that has to do with people voluntarily taking measures to protect others, not just themselves. Telling people that they should stay home when they're feeling sick, or that they should get vaccinated, is really more about their not making somebody else get sick. So public health is asking people to sacrifice their personal preferences and interests for the sake of others and sometimes telling people they have to do that; it's kind of like an enforced altruism. So how does bioethics deal with this? It starts by acknowledging that this is about asking or requiring people to recognize that we are part of a system in which we limit some aspect of our liberties for the sake of others.

Vaccine mandates are stirring controversy and being litigated. Is it ethical to require vaccination as a condition of employment or to attend college?

Charo: I want to separate some of the issues that are buried in that question. I want to separate ethics from law, because there are some legal rules that apply here, and although legal rules and ethics rules often overlap, they're not exactly the same.

I also want to distinguish between school and employment. With employment, if your viral status poses a threat to others and is inconsistent with the very essence of your position, it becomes pretty straightforward to say we're going to require that you'll be vaccinated. That's where health care workers become a very special population. They are in contact with people who are vulnerable medically, and the very nature of their profession is helping people to be healthy. So putting

patients at a health risk is really completely inconsistent with the very nature of the job. In those cases, in terms of the law, you'll have the easiest job justifying why somebody could be released from employment—and that was exactly what a federal judge recently found with regard to a hospital in Texas.

When it comes to school, I think it becomes a little bit more complicated because the risk is no longer a risk that you're imposing on people who are all vulnerable. In addition, your position as a student or faculty member is not fundamentally about keeping other people healthy. I find it a little harder here to justify an outright prohibition on the unvaccinated, because many measures can be taken to reduce the risk of transmission, such as frequent testing, masks, perhaps isolated seating areas. Also, at many colleges there is a kind of esprit de corps, a sense of being in it collectively. For students who are activated over climate change, for example, or about abuses of people who are poor or marginalized, this is an opportunity for them to see public health in the

among humans. This has always been controversial, but may be even more so now. Has the pandemic changed your thinking about this kind of research?

Charo: At the core of this question is something that is beyond my capabilities, which is evaluating scientifically how crucial is it that we do gain-of-function experiments. (I want to say, as an aside, that the people in this field hate the phrase “gain-of-function” because it is not precise enough for the kinds of things they are dealing with.) I've watched this argument for a long time. Some say it's dangerous to do this kind of research because we might be creating a cookbook for somebody with nefarious purposes or because it puts us at high risk for an accident. On the other hand, there are those who say you can't build a countermeasure without understanding what you're fighting. That's beyond my ability to assess.

I think that even people who are of the opinion that you need to continue this research, for valid scientific

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same way. I think you can still make the argument that you have a duty to others. I have no problem with that, but I hope we'll look for every measure short of legal requirements.

Have we done enough to share vaccines with the developing world?

Charo: No. The answer is simply no. If we're going to talk about being in it collectively, then we are in it collectively all across the globe. Politically, I understand that it is very hard to place the interests of people outside the country ahead of those inside. And until the most vulnerable populations in the United States have been reached, it is even harder to justify sending vaccines offshore. But I think more than anything else, COVID-19 has really driven home the reality that disease does not recognize political borders.

Speculation about the origin of the virus has cast a light on so-called gain-of-function research in which genes of viruses are altered to understand how they may evolve in ways that could make them more transmissible

reasons, would agree that we need a system in which you have much more public knowledge of what the criteria are for deciding whether an experiment is, or is not, too dangerous or too problematic to publish in its entirety. We have a process for individualized review of potentially risky experiments, and we need that to be more transparent. We need to develop some degree of not only public trust, but public oversight. But I'm not ready to say that we should or should not have these experiments—because that's just not something I'm qualified to speak to.

Do you think the pandemic will change public perception of the risks and benefits of biotechnology?

Charo: I hope it does. For a very long time, we have had a very compartmentalized approach to national security versus public health: they existed in separate offices within international organizations and in separate departments within our own government. We did not treat public health as a national security priority.

I think COVID-19 has brought home that whether it's intentional, accidental, or natural, the same

pathogens that affect our public health also put a stress on our national security. Our economy was affected in ways that will take years to recover from; we learned that our supply chain is very fragile, which made us very vulnerable.

This is an opportunity for people to see that there is a real intersection here, and that we can promote innovative biotechnology while at the same time inserting biosecurity and biosafety into every part of the field, academic and industrial, from the very beginning.

You have been at the center of many national and global debates about the appropriate use of new discoveries in the biological sciences, going back to stem cells and cloning in the 1990s, to CRISPR, chimeras, gene drives, synthetic biology, and so on today. How has the role of bioethics in these debates changed over time?

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Charo: It’s almost as if bioethics is beginning to come full circle. Bioethics, in its earliest days in the 1960s—when the word itself was still brand-new—was more about environmental ethics. That morphed into something that became very much about doctor-patient clinical care: talking about the relationship between the patient’s preferences and the doctor’s professional expertise. Lawyers got involved because they’re able to talk about which social controls to put on those relationships—whether it’s standards of care or standards for informed consent.

Yet soon biotechnology innovations went beyond the physician’s and individual patient’s choice, to affect all of society. They were innovations that had an effect on others in a very significant way. Reproductive technologies, for example, would change the fabric of families to the point where we had to acknowledge that some families have genetic parents as opposed to gestational ones. The law needs to keep up with that. And it requires us to think more broadly about what’s the best way to protect the interests of children. Should the government be funding certain research and, if so, under what conditions? We began to realize

that these are bigger social decisions—and then I think bioethics really expanded into the ethics of public policy.

Let’s take the debate over physician-assisted dying for terminally ill patients. We can have very fundamental disagreements about whether people should control the timing and nature of their deaths, a lot of which tend to turn on religious views. At that point, bioethics has to turn into political ethics, which is the ethics of how you govern a civil society where people have fundamental differences. You can have majoritarian rules in which minority viewpoints are squelched, or you can have a system in which minority viewpoints are privileged and everybody can do what they want as long as they don’t actually hurt somebody—or you can have a system somewhere in between. These are the ethics of decisionmaking and of how to organize a civil society.

I think bioethics is slowly beginning to recognize that the answers to some of these dilemmas don’t lie in the technology; they lie in the political system. Take

a technology like reproductive cloning. I remember sitting in a meeting of representatives of various national bioethics commissions talking about whether there could be a common global viewpoint on this, and it became clear to me that we were never going to agree on the rights and wrongs of cloning per se. What was really going to happen is that it was going to be the political presumptions of liberty versus nonliberty that were going to determine what happens with that technology.

I wish that more bioethics addressed this more explicitly. We really should be talking about an ethics of policymaking, not just the bare-knuckle politics of policymaking.

When you talk about the ethics of policymaking, whose ethics are you talking about?

Charo: The philosophers would give you a different answer than I would; they might talk about some system for deriving a set of ethical principles that we can all agree to. As a lawyer, I truly do look to the Constitution—not for the actual words, as the Supreme Court works on that for us—but for what I call a

“constitutional culture.” Our Constitution, from my perspective, has built into it a feeling of collective benefit that is always in tension with personal liberties. When you are looking at that balance, you give preference to personal liberty until there is a strong reason, a strong collective interest, in limiting that freedom. There is a real tolerance for eccentricity and minority viewpoints; in fact, the very structure of our system is designed to protect the interests of minority viewpoints. So I think the country’s constitutional structure is the place to start to search for ethics of policymaking.

You were in Hong Kong with the organizing committee for the Second International Summit on Human Genome Editing when He Jiankui revealed that he had used CRISPR to edit the embryos of twin girls. Do you think that was a turning point in how we think about the governance of these breakthrough discoveries that have such profound societal implications?

Charo: I think it gave everyone interested in this field—scientists and nonscientists alike—a great sense of urgency. When we finished our National Academies report on the governance of genome editing in early 2017, it laid out a fairly extensive set of conditions that would have to be met before any responsible governing system should even consider allowing somebody to go forward with heritable editing. The conditions were viewed by most to be so stringent that there was no way they could be met at the time. We understood that not everybody may abide by them, but we thought we had more time to create a more generalized agreement among regulators around the world.

When Jiankui made his announcement, it became apparent that this was moving faster than the building of any kind of governance system within or among countries. That led very specifically to two separate efforts. One was an international commission that came out with a report focused on very precise limits on which diseases should, if ever, be targeted if you allow germline editing. (And of course, no one has to allow it.) The second effort, which is coming to fruition just now and will be released very shortly, is from an expert committee of the World Health Organization, that I am on, in which we are looking more specifically at what would it take to have responsible governance, what capacities a regulatory system needs, and what to anticipate when it comes to cross-border coordination of countries that have different rules. It’s my hope that these two efforts together will help countries move more rapidly than they could have otherwise.

Are scientists sufficiently trained to appreciate the ethical implications of the research they may pursue?

Charo: In the twentieth century, physicists and engineers became very much aware of the ways in which their fundamental work could be used for military purposes. The explosion of atomic bombs and subsequent developments gave them a real understanding of the power of what they were doing. There was an active debate in the physics community about whether some research should not be done at all. In the twenty-first century, biologists are beginning to have that same awakening—that what seems like purely basic bench science might possibly turn into something that has tremendous societal effects. If you’re a bench scientist, though, what you’re doing is often many degrees of separation away from these applications. Discussing the societal control of the research is just so far off and distinct from what these biologists are doing that it seems completely theoretical.

In some ways, I think it would be better not to teach ethics, but to teach history. Give scientists a more concrete and visceral understanding of how what they’re doing in the lab today could develop, over time, into something that transforms a whole society. It starts with being aware of the potential of what you’re doing.

Bioethics tries to manage scientific and medical advances in a way that improves people’s lives. But has the field done enough to give proper consideration to whether these advances are improving everyone’s lives, that they are benefiting all segments of society?

Charo: No, it has not. To become obsessed with the doctor-patient relationship in the 1970s, when many people didn’t even have access to a doctor, tells you something. And today, after the tragic events of the past year, we can see clearly that not everyone in this society has been at the table, helping to determine what bioethicists view as important. There is now an incredible surge of interest within every field—and bioethics is no exception—of trying to diversify. I think the diversification of the field is underway in a very, very slow way; but it is happening.

But at another level, I think there’s beginning to be more awareness of the planetary questions that should be part of bioethics. And that’s why I was saying before that in a sense we’re starting to come full circle back to the field’s early environmental beginnings.